Medical Device Services

Specializing in FDA Regulatory Matters

EAS CONSULTING GROUP

EAS Consulting Group, LLC is a leading provider of regulatory services to the medical device, pharmaceutical, food, dietary supplement, tobacco, and cosmetic industries. Originally founded in 1960, EAS has over 50 years of experience assisting clients in developing regulatory strategies, implementing quality systems, filing regulatory submissions, and ensuring compliance with all Food and Drug Administration (FDA) regulations. Employing a unique team of former FDA officials and industry experts, many with more than 30 years of experience, EAS has unparalleled expertise to assist clients with all of their consulting needs.

Whether your product is a class I, II or III device, EAS Consulting Group, LLC. has the expertise to provide wide-reaching guidance as well as act as a conduit between manufacturers and marketers of devices and FDA.

No matter the type of device, whether your company is in need of a 510(k) Premarket Clearance, IDE, QSR audit, US Agent or registration assistance or the filing of petitions, exemptions and responding to warning letters and 483s, EAS can help.

- ✓ Regulatory Strategy Development
- ✓ Regulatory Compliance
- ✓ 510(k) Pre-Market Clearance, De Novo and PMA submissions
- ✓ ISO 13485 QSR and FDA GMP harmonization
- ✓ CAPA, FDA 483 & WL Remediation
- ✓ Facility and SOP Audits
- ✓ Label Assistance
- ✓ Design History and Device Master Files
- ✓ Seminars and Onsite Trainings

EAS Consulting Group, LLC
www.easconsultinggroup.com

EAS Consulting Group, LLC provides medical device consultation services to assist you with GMP compliance, plan for new product development, take your new product through the regulatory evaluation process and obtain market approval from regulatory bodies.

EAS provides a full spectrum of consulting services. Our Independent Consultants have spent a significant portion of their professional careers working at FDA and/or working in industries regulated by the Agency. It is this first-hand experience that sets EAS apart from others in the industry.

Strategic Product Development

Whether you need assistance with FDA regulatory strategies for device development; pre-market submission and FDA approval or clearance; a pre-clinical study and clinical protocol development plans; preparation of, or assistance with, premarket notifications (510(k)s); investigational device exemption (IDE) applications and premarket approval (PMA) applications; or hazards and risk analyses, we have the experts to help. Our Independent Consultants have detailed knowledge of federal/state regulations and compliance procedures.

Regulatory Compliance

If you need help with an FDA establishment registration and device listing, quality system and program development, including design controls or medical device reporting, our experts can help. Our staff can also lend their expertise with post market (FDA) study requirements, GAP audit and analyses against regulatory requirements, GMP/quality system procedure development, preparing responses to FDA inspection observations and issues, assisting with the implementation of corrective or device recall actions, and preparing master files.

Auditing Services

Independent Consultants include FDA investigators who participated in the EAS Consulting Group were FDA investigators prior to joining our company and participated in the implementation of the first device CGMPs and the comprehensive revision of regulations in 1996, while others have many years of industry experience in device quality systems. Our Independent Consultants perform Quality System audits against FDA regulatory requirements; bioresearch/clinical trial auditing; vendor audits; mock FDA inspections, as well as due diligence audits.

Seminars and Onsite Training

At EAS we pride ourselves on our ability to conduct training courses tailored to the needs of your organization. Our Independent Consultants will travel to your facilities for a reasonable cost, and train your staff on premarket evaluation processes, quality system and medical device regulatory requirements, FDA inspection process, and preparation for meetings with regulatory agencies. We also conduct public training seminars at convenient locations throughout the US and abroad.

Students who have attended our training programs and seminars have found EAS training to be unique, in that they have an opportunity to ask former regulators questions that simply cannot be addressed by other training organizations. You will find our training sessions on medical devices to be extremely beneficial.

Label Assistance

EAS' labeling staff is highly experienced in the specialized requirements for medical device labels. With our detailed knowledge of FDA labeling requirements we can review your label for formatting and claims and advise you on how to be in compliance.

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